

PATENT  
144002-2001**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Douglas T. DIETERICH  
 Serial No.: 09/862,404  
 Filing Date: May 21, 2001  
 For: **METHOD OF TREATING ANEMIA CAUSED BY RIBAVIRIN  
 TREATMENT OF HEPATITIS C USING ERYTHROPOIETIN ALPHA**  
 Examiner: Canella, K.  
 Art Unit: 1642

745 Fifth Avenue, New York, NY 10151

**EXPEDITED PROCEDURE  
 RESPONSE AFTER FINAL  
 UNDER 37 C.F.R. 1.116****EXPRESS MAIL**

Mailing Label Number: EV206802969US

Date of Deposit: April 7, 2004

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

CHARLES JACKSON

(Typed or printed name of person mailing paper or fee)

Charles Jackson

(Signature of person mailing paper or fee)

**DECLARATION**

**Mail Stop AF**  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450  
 Dear Sir:

PAUL KLOTZMAN

, declares and states that:

1. I understand that I have been provided with a copy of the above application ("the present application") as published (Exhibit A), a copy of claims being advanced (Exhibit B), and a copy of Bruchfeld *et al.* ("Management of ribavirin treatment in renal insufficiency and dialysis," September 2000, Journal of the American Society of Nephrology, Vol. 11, Program and Abstract Issue, page 57) ("Bruchfeld") (Exhibit C). I have read and understand the documents of

PATENT  
144002-2001

Exhibits A, B and C. A copy of my *Curriculum vitae* is attached as Exhibit D. I respectfully submit that I am considered by my peers to be a person skilled in the art to which the present application pertains, and am qualified to speak about the documents of Exhibits A, B and C, based upon my education, training, and experience, and that I have read and understand them.

2. In my opinion, Bruchfeld does not teach or suggest treating hepatitis C in an HIV-negative patient in need thereof comprising administering ribavirin (RBV) or RBV and interferon-alpha (IFN), wherein the improvement comprises administering Erythropoietin (EPO) concomitantly or sequentially or via co-administration with the RBV or with the RBV and IFN and the RBV is administered at a maximum effective of dosage 800 to 1200 mg per day; and, would not direct the skilled artisan to such treatment. And, Bruchfeld, in my opinion, does not teach or suggest treating ribavirin or ribavirin and interferon-alpha induced anemia in hepatitis C patients comprising administering erythropoietin to a patient in need thereof as a liquid preparation subcutaneously, parenterally, intradermally, intramuscularly or intravenously wherein the ribavirin or ribavirin and interferon-alpha induced anemia is a result of treating said hepatitis C patients with a maximum ribavirin effective dosage of dosage 800 to 1200 mg per day; and, would not direct the skilled artisan to such treatment.

3. For instance, Bruchfeld does not teach or suggest employing doses of 800 to 1200 mg per day. Rather, Bruchfeld employed lower doses than 800 to 1200 mg per day. Moreover, Bruchfeld expressly teaches administering reduced dosages of RBV, in particular, administering 170 to 300 mg of RBV per day for dialysis patients and about 200 to 600 mg per day for kidney transplant patients. This is up to seven times less the amount of RBV than doses of 800 to 1200 mg per day. And I find the patient population in Bruchfeld to be comparable to HCV patients that are not on dialysis or did not have a kidney transplant because the patient population in Bruchfeld received iron as a supplement. Also, by expressly requiring and utilizing lower RBV dosages, Bruchfeld is constant with the state of the art (reduction of RBV dose to address anemia); and therefore, I find that Bruchfeld teaches away from employing RBV doses of 800 to 1200 mg per day. In this regard, I note that Bruchfeld expressly, "requires reduced ribavirin doses as well as close monitoring of ribavirin concentration" (emphasis added), contrary to employing RBV doses of 800 to 1200 mg per day.

4. Furthermore, Bruchfeld states that, "4/5 dialysis patients became HCV-RNA negative during treatment, but relapsed post-treatment," such that in my opinion, Bruchfeld is

PATENT  
144002-2001

not teaching or suggesting any treatment of HCV or RBV or RBV+IFN-alpha anemia in HCV patients, since Bruchfeld teaches that her patients relapsed. In contrast, the present application and invention (Exhibits A, B) provide methods for actually treating HCV-infected patients. The present application and invention provides for administering RBV doses greater than 80% (10.6 mg/kg per day) [i.e., greater than 800 mg per day for a 165 pound patient] of the recommended dose, and hence provides a method for actually treating HCV-infected patients.

5. I further declare that all statements made herein, of my own knowledge, are true and that all statements made on information and belief are believed to be true and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date:

4/7/2004Paul KlotmanPaul Klotman

(print name)

**CURRICULUM VITAE**

August, 2003

**Name** Paul E. Klotman, M.D.  
Murray M. Rosenberg Professor of Medicine  
Chairman, Samuel Bronfman Department of Medicine  
The Mt. Sinai Medical Center, New York

**Mailing Address** 387 West End Avenue  
New York, NY 10024

**Telephone Number (W)** 212-241-4200  
**Date of Birth** July 26, 1950

**Place of Birth** Cleveland, Ohio

**Social Security #** 298-44-4006

**Spouse:** Mary Frances Earley Klotman  
Chief, Division of Infectious Diseases  
Irene and Dr. Arthur M. Fishberg Professor of Medicine  
Mount Sinai Medical Center, NY

**Children** Samuel Eric Klotman, Born April 14, 1989  
Alexander Isadore Klotman, Born November 15, 1990

**Citizenship** USA

**Education**  
B.S. 1972 University of Michigan, Ann Arbor, MI  
M.D. 1976 Indiana University Medical School, Indianapolis, IN

**Postdoctoral Training**  
1976-77 Intern, Dept. of Medicine, Duke University Medical Center  
1977-78 Jr. Asst. Res., Dept. of Medicine, Duke University Medical Center  
1978-79 Sr. Asst. Res., Dept. of Medicine, Duke University Medical Center  
1979-80 Research Fellow, Div Nephrology, Duke University Medical Center  
1980-81 Chief Medical Resident - Dr. James Wyngaarden Chairman,  
Duke University Medical Center  
1981-82 Research Fellow, Div Nephrology, Duke University Medical Center

**Academic Appointments**  
1980-1982 Associate in Medicine, Department of Medicine, Duke University  
1982-1988 Assistant Professor of Medicine and Nephrology, Duke University  
1988-1989 Associate Professor of Medicine and Nephrology, Duke University  
1989-1993 Section Chief, Molecular Medicine  
Laboratory of Developmental Biology/NIDR/NIH  
1993-1994 Tenured Intramural Section Chief, Viral Pathogenesis  
Laboratory of Oral Medicine/NIDR/NIH  
1994-2001 Irene and Dr. Arthur M. Fishberg Professor of Medicine  
The Mt. Sinai Medical Center, New York  
1997-2001 Vice Chairman for Research, Department of Medicine  
The Mt. Sinai Medical Center, New York  
1998-Present Professor of Immunobiology  
The Mt. Sinai Medical Center, New York  
1998-Present Professor of Gene Therapy

2001-Present

The Mt. Sinai Medical Center, New York  
Murray Rosenberg Professor and  
Chairman, Samuel F. Bronfman Department of Medicine  
The Mt. Sinai School of Medicine, New York, NY

**Hospital Appointments**

1976-89

VA Staff Physician, Veterans Adm. Med. Center, Durham, NC  
(GS 15-5, 7/1/76 - 7/1/89)

1976-93

Staff Physician, Duke University Hospital, Durham, NC

1980-82

Duke Hospital Executive Committee, Durham, NC

1980-82

Pharmacy & Therapeutics Committee, Duke Hospital, Durham, NC

1984-88

Director, Duke University Hypertension Center, Durham, NC

1995-Present

Chief, Division of Nephrology, Mt. Sinai Medical Center

1995-Present

Attending Physician and Director Dialysis Services  
Mt. Sinai Medical Center

2001-Present

Chief of the Medical Service, Mt. Sinai Medical Center, New York, NY

**Board Certification**

1979

Diplomat of the American Board of Internal Medicine #70820

1984

Diplomat of the American Board of Internal Medicine  
Subspecialty - Nephrology #70820

**Licensure**

July 1995

New York License # 199427-1

**Honors and Awards**

University of Michigan (1968-1972)

1972

Phi Beta Kappa, University of Michigan

Indiana University Medical School (1972-1976)

1973

Public Health Service Research Award

1975

Alpha Omega Alpha - Junior Year

1976

Academic Achievement Award, Indiana University

1976

Mosby Scholarship for Academic Achievement

1976

Upjohn Academic Achievement Award

1976

AMSA-UTMB Natl. Student Research Award Am. Heart Assoc.,

1976

Culpepper Foundation Research Award, Indiana Univ. Med. School

Postgraduate (1976-Present)

1977-79, 81, 86

Recognized by Medical Student Body for Excellence in Teaching

1985

Housstaff Teacher Recognition Award

Duke University Medical Center, Department of Medicine

1988-89

NIH Visiting Scientist

1988

Henry Christian Award for Medical Research-AFCR (Nephrology)

1991

Henry Christian Award for Medical Research-AFCR (Nephrology)

1992

Henry Christian Award for Medical Research-AFCR (Dermatology)

1993

Henry Christian Award for Medical Research-AFCR (Infect. Dis.)

1993

Elected to American Society of Clinical Investigation

2001

Elected to Association of American Physicians

**Professional Societies**

1982-Present

American Federation for Clinical Research

1986-1989

Councillor, Southern Section, AFCR

1982-Present

American Society of Nephrology

1982-Present

International Society of Nephrology

1983-Present	American Physiological Society
1987-1994	Southern Society of Clinical Investigation
1992-Present	American Society for Microbiology
1993-Present	American Society of Biochemistry and Molecular Biology
1993-Present	American Society of Clinical Investigation
1996-Present	American Society for Virology
1998-Present	American Society of Gene Therapy
2001-Present	Association of American Physicians
2001-Present	Association of Professors of Medicine

# Training Record

<u>Trainee</u> Coffman, Thomas	<u>Pre/Post</u> Post	<u>Training Period</u> 7/83-6/85	<u>Prior Ed</u> M.D.	<u>Source of Support or Current Position</u> Chief, Division of Nephrology, Duke University James Clapp Professor of Medicine & Nephrology Duke University Medical School
Earley, Mary	Post	7/83-6/85	M.D.	Chief, Division of Infectious Diseases, Mt. Sinai Medical Center Irene and Dr. Arthur M. Fishberg Professor of Medicine & Infectious Diseases
Smith, Stephen	Pre	7/84-6/86	M.D.	Associate Professor of Medicine & Hypertension Duke University Medical School
Svetkey, Laura	Post	7/84-6/87	M.D.	Director, Duke Hypertension Center Professor of Medicine & Nephrology, Duke University Medical School
Collins, Deirdre	Post	7/86-6/88	M.D.	Private Practice in Nephrology
Spurney, Robert	Post	7/87-6/89	M.D.	Associate Professor of Medicine, Duke University Medical School
Horikoshi, Satoshi	Post	6/89-3/91	M.D.	Asst. Chief of Nephrology, Juntendo University, Japan Professor of Medicine
Bruggeman, Leslie	Post	1/89-7/91	Ph.D.	Associate Professor of Medicine Case Western Reserve University
Ray, Patricia	Post	12/90-12/93	M.D.	Professor of Pediatrics, George Washington Univ. Med School
Kopp, Jeffrey	Post	1/90-6/94	M.D.	Intramural NIH Research Officer 05, PHS, NIDDK, NIH
Yang, Kamie	Pre	6/92-6/93	NA	University of Pennsylvania Medical student MSIII
Adler, Scott	Pre	7/91-7/93	M.D.	Instructor, Department of Medicine, University of Pennsylvania, Philadelphia, PA
Rappaport, Jay	Post	1/92-8/96	Ph.D.	Professor of Neurovirology, Temple Medical School Associate Director of Molecular Virology Laboratory

Harass, Basil	Post	7/93-6/95	Ph.D.	Asst. Professor of Medicine & Physiology, Mt. Sinai Med. Center, NY
Greenwald, Daniel	Pre	6/93-7/95	M.D.	Chief Resident in Medicine, Stanford University
Teixeira, Avelino	Post	7/95-Present	Ph.D.	Research Assistant Professor of Medicine Mt. Sinai Medical Center, NY
Cohn, Michael	Pre	6/94-7/96	M.D.	Resident in Medicine UCSF
Gharavi, Ali	Post	6/96-6/97	M.D.	Assistant Professor of Medicine, Columbia Physicians and Surgeons, NY
Ross, Michael J.	Post	7/99-6/01	M.D.	Asst. Professor of Medicine, Mt. Sinai Medical Center KO8
Ross, Michel D.	Pre	Ph.D. Awarded 10/02		MSTP Student, Mt. Sinai School of Medicine
Schwartz, Elissa	Pre	Ph.D. Awarded 6/02		Post Doc UCLA, Dr. Sally Blower
Marras, Daniele	Post	7/00-6/02	Ph.D.	Staff Scientist, Institute for Virologic Research, Genoa Italy
He, Cijiang	Post	2000-2002	M.D., Ph.D.	Asst. Professor of Medicine Mt. Sinai School of Medicine KO8
<u>Current Post Docs in the Laboratory</u>				
Husain, Mohammad	Post	Current	Ph.D.	Supported: NIH Grant Winner of the National Kidney Foundation Young Investigator Award (NY/NJ) 2000
Sumimoto, Masaki	Post	Current	Visiting M.D.	Kyoto University Supported NIH Grant
Monahan, Marianne	Post	Current	M.D.	Supported by Renal Fellowship
Hayashi, Kayo	Post	Current	Visiting M.D.	Supported by a Grant from the Japanese Kidney Foundation



**Previous Grant Support**

Year	Amount/Yr.
1980-81	\$20,000/year
	\$40,000 Total
1980-86	\$250,000/year
	\$1,000,000 Total
1983-90	\$120,000/year
	\$840,000 Total
1986-89	\$45,000/year
	\$135,000 Total
1988-93	\$650,000/year
	\$3,250,000 Total
1988-94	\$500,000/Year
1996-97	\$15,000/year
7/97-6/99	\$25,000
1996-2001	\$1,000,000/yr

**Source**

National Kidney Foundation Research Fellowship  
Duke University Medical Center, Durham, NC  
Consultant and Research Contracts  
Pfizer, AH Robbins, American Cyanamide,  
Hoffman LaRoche  
Merit Review, Veteran's Administration (PI)  
Renal Prostaglandin Metabolism  
National Institute of Aging (CoPI)  
CoPI: Hypertension in Elderly Blacks  
NIH-PPG: PI: Pathophysiology of Renal  
Allograft Dysfunction in the Rat - (PI)  
Tenured Intramural Scientist  
AMFAR: Growth failure in HIV transgenic mice  
NKF fellow      Cloning a 72kDa DNA channel (M. Sedlacek)  
NIDDK: PPG Gene Therapy for Renal Disease

## OTHER SUPPORT 2001

Paul Klotman, M.D.

Paul Klotman, M.D.

**ACTIVE**

5 T32 DK07757-03 (Klotman, Paul E.)

Source: National Institutes of Health NIDDK

Institutional National Research Service Award

Title: Molecular Basis of Renal Disease

7/1/98-6/30/03

\$84,695

0%

The objective of this project is to train talented young physician-scientists for a successful career in investigative nephrology.

1 P01 DK56492-04 (Klotman, Paul E.)

Source: National Institutes of Health/NIDDK

35% Total

Title: Pathogenesis of HIV-Associated Nephropathy

9/15/99-6/30/04

\$1,156,423

The major goals of this project are

1. To identify candidate genes methods that may be responsible for enhancing the severity of HIVAN or its phenotypic penetrance by position cloning.
2. To explore mechanisms of viral pathogenesis including the evolution of renal quasispecies, the mechanisms of viral entry, and the steps in the viral life cycle supported by the renal epithelia.
3. To explore viral-host interactions by determining which viral gene product(s) are responsible for initiating HIVAN and the host response to infection using representational difference analysis to identify candidate pathways.

1 R01 DK63610-01 (Klotman, Paul E.)

Source: National Institutes of Health/NIDDK

Title: Mechanisms of Nucleic acid Uptake by Renal Epithelium \$404,681

06/20/2002 - 03/31/2006

25% effort

The major goal of this project is to explore how strands of DNA enter cells. We have previously shown that single stranded DNA can move through a highly specific channel. We purified this protein complex and have been identifying what each component of this complex does. We have now identified one of the subunits of this channel as a common enzyme that serves also to regulate DNA uptake. The current proposal will evaluate other subunits and participant sin this activity.

**PENDING**

None

# Patents

1. Klotman PE, Bruggeman LA, and Horikoshi S. Method for quantifying laminin and beta actin mRNA. US Patent 07/929,204. Awarded November 26, 1993.
2. Rappaport J, Arya S, Klotman P. Use of HIV-2 as molecular therapy for HIV-1. Patent pending
3. Teixeira A, Klotman PE. Modified Anthrax delivery vehicles. Pending.
4. Hanss B and Klotman PE. Nucleic acid channels. Pending.
5. Gelman I and Klotman PL. Small molecules to inhibit Nef in the treatment of HIV complications. Pending

# Visiting Professorships

- |       |  |
|-------|--|
| 1986  | Division of Nephrology, Columbia University, New York, NY                        |
| 1989  | Department of Medicine, University of Wisconsin Medical Center, Madison, WI      |
| 1990  | Division of Nephrology, Emory University, Atlanta, Georgia                       |
| 1990  | Department of Medicine, Medical University of South Carolina, Charleston, SC     |
| 1990  | Department of Medicine & Division of Nephrology, Juntendo Univ., Tokyo, Japan    |
| 1990  | Johns Hopkins University School of Medicine, Baltimore, MD                       |
| 1990  | University of California San Diego, La Jolla, CA                                 |
| 1991  | Div of Nephrology, Univ of Pennsylvania School of Medicine, Philadelphia, PA     |
| 1991  | Columbia University College of Physicians and Surgeons, New York, NY             |
| 1992  | Division of Nephrology, Montefiore and Albert Einstein Medical Centers           |
| 1992  | Dept. of Anatomy & Cell Biology, Medical Univ South Carolina, Charleston, SC     |
| 1992  | Dept. of Medicine and Div of Nephrology, Duke Univ Medical Center, Durham, NC    |
| 1993  | Department of Medicine and Division of Nephrology, Johns Hopkins, Baltimore, MD  |
| 1993  | Molecular Medicine Institute, Jefferson Medical College, Philadelphia, PA        |
| 1996  | Division of Nephrology, Dept. of Medicine, Columbia University, New York, NY     |
| 1996  | Department of Pathology, Yale University, New Haven, CT                          |
| 1996  | Division of Nephrology, Duke University Medical Center, Durham, NC               |
| 1997  | Department of Medicine, New York University Medical Center, New York, NY         |
| 1997  | Department of Medicine, New York Medical College, Valhalla, NY                   |
| 1998  | Division of Nephrology, Duke University Medical Center, Durham, NC               |
| 1999  | UCLA Max Martin Salick Visiting Professor, Torrance, CA                          |
| 4/00  | Division of Nephrology, UT Southwestern Medical Center, Dallas, TX               |
| 5/00  | Division of Nephrology, Indiana University Medical School, Indianapolis, IN      |
| 8/00  | Division of Nephrology, Duke University, Durham NC                               |
| 11/01 | Department of Medicine, UC San Diego, San Diego CA                               |
| 1/02  | Division of Nephrology, University of Colorado, Denver CO                        |
| 2/02  | Department of Medicine, Northwestern University, Chicago IL                      |
| 5/02  | Department of Medicine, Albert Einstein College of Medicine, Bronx, NY           |
| 1/03  | Ike Robinson Visiting Professorship, Duke University Medical Center, Durham, NC  |
| 9/03  | NKF Saulo Klahr Lecture, Washington University School of Medicine, St. Louis, MO |
| 1/04  | CFAR Lecturer, Department of Medicine, Vanderbilt University, Nashville TN       |

# Invited Lectures at National and International Meetings and Symposia

- |      |  |
|------|--|
| 1986 | Southeastern Organ Procurement Foundation, Tampa, FL<br><i>"Role of Thromboxane in Renal Allograft Rejection"</i>  |
| 1986 | Alexis Carrel Symposium, Georgetown Med Cntr, Washington, DC<br><i>"Lipid Mediators in Renal Allograft Rejection"</i>  |
| 1986 | National Kidney Foundation, Charlotte NC<br><i>"Prostaglandins in Diabetic Renal Disease"</i>  |
| 1987 | American Society of Nephrology, Washington, DC<br><i>"Thromboxane Receptors and Inhibitors"</i>  |
| 1988 | International Symposium on the Prevention, Treatment & Diagnosis of Acute Renal Failure, Edmonton, Alberta, Canada, <i>"Thromboxane and Renal Dysfunction"</i> |
| 1989 | American Society of Nephrology, Washington, DC<br><i>"Molecular Mechanisms of Cyclosporin Toxicity"</i>  |

- 1990 NIH Research Symposium  
Workshop on Polypeptide Mediators of Inflammation & Repair, Bethesda, MD  
*"Role of Eicosanoids in Extracellular Matrix Gene Expression"*
- 1991 NIH Highlights from the NIDR  
*"HIV Associated Nephropathy in Transgenic Mice"*
- 1991 Intl. Conf on the Molecular bases of Hepatic Cirrhosis, INSERM, Rennes, France.  
*"Progressive renal failure: role of extracellular matrix proteins"*
- 1992 National Institute of Aging, Baltimore, MD  
*"Transgenic Models of Viral Disease"*
- 1992 Laboratory of Tumor Cell Biology Annual Meeting, Bethesda, MD  
*"Transgenic Mice as Models for HIV Pathogenesis and Therapy"*
- 1993 Sixth Int. Symposium on Basement Membrane, Fuji Conference Cntr, Shizuoka, Japan  
*"Potential roles for bFGF and TGF- $\beta$  in the pathogenesis of AIDS-associated nephropathy in transgenic mice"*
- 1993 American Society of Nephrology, Boston, MA  
*"Gene Therapy Symposium"*
- 1993 New York Society of Nephrology, New York, NY  
*"Pathogenesis of HIV Associated Nephropathy"*
- 1994 American Society of Nephrology, Orlando, FL  
*"Molecular Biology Symposium: Advances in Gene Therapy"*
- 1994 American Society of Nephrology, Orlando, FL  
*"HIV-1 and the Kidney"*
- 1996 Harvard Medical School CME Course, Beth Israel, Boston, MA  
*"HIV Associated Nephropathy"*
- 1996 Harvard Medical School CME Course, Brigham and Women's Hospital, Boston, MA  
*"New Insights into HIV Associated Nephropathy"*
- 1997 Harvard Medical School CME Course, Brigham and Women's Hospital, Boston, MA  
*"Pathogenesis of HIV associated nephropathy"*  
*"Gene Therapy"*
- 1997 Japanese Society of Nephrology, Niigata, Japan  
*"Transgenic Models of Renal Disease"*
- 1997 International Congress of Nephrology, Sydney Australia  
*"Transgenic Models of Renal Disease"*
- 1997 Harvard Medical School CME Course, Beth Israel, Boston, MA  
*"Clinical Update: HIV associated nephropathy"*
- 1997 American Society of Nephrology, San Antonio Texas  
Symposium Director: Clinical Issues in HIV Associated Nephropathy  
*"Advances in HIV Pathogenesis and Therapy"*
- 1998 Harvard Medical School Symposium: From Bench To Bedside  
Brigham and Women's Hospital, Boston, MA  
*"Updates in HIV associated nephropathy"*  
*"Molecular Therapy"*
- 1998 Harvard Medical School CME Course, Beth Israel, Boston, MA  
*"Clinical Update: HIV associated nephropathy"*
- 1998 ACTG Investigators Meeting, San Francisco, CA  
*"Nucleotide analog-induced Fanconi Syndrome"*
- 1998 International AIDS Society, New York NY  
*"Renal Complications in HIV Disease"*
- 1998 Scientific Session of the Consortium for Southeastern Hypertension Control  
*"Genetic factors that influence the development of HIVAN in African Americans"*
- 1998 World Health Communications: Comprehensive Management of HIV Disease  
*"Novel HIV therapeutics: Adefovir"*
- 1998 Molecular Biology Course: ASN  
*"Gene Therapy"*
- 1998 Columbia University Pathology CME Course  
*"Clinical and Pathological Features of HIV associated nephropathy"*

- 1999 Harvard Medical School CME Course, Beth Israel, Boston, MA  
"HIV associated nephropathy"
- 1999 German Society of Nephrology  
State of the Art Lecture: "AIDS and the Kidney"
- 1999 Columbia University Pathology CME Course  
"Clinical and Pathological Features of HIV associated nephropathy"
- 6/1/00 Organizer: International Society of Nephrology  
Frontiers in Nephrology: Gene Therapy
- 8/19/00 Int'l. Society of Hypertension: End State Renal Disease - Genetics to Therapy  
"Gene Therapy in Kidney Disease"
- 3/19/02 Optimal Management of HIV Disease: Clinical Conference  
Management of renal disease in HIV-1 patients
- 9/26/02 HIV Nephropathy  
Post Graduate Medical Conference, Columbia University College of Phys & Surgeons
- 12/3/02 Adefovir Management  
Japanese Regulatory Agency for Drug Development
- 11/14/03 "Has HAART altered the course of HIVAN?"  
Virus-associated Glomerulopathies Symposium  
American Society of Nephrology, San Diego, 2003
- 12/4/03 Animal Models for HIV associated nephropathy  
Workshop on Animal Models for Studying HIV Pathogenesis  
Center for Neurovirology and Cancer Biology, Temple University, Medical Center

#### Editorial Boards

- 1991-95 American Journal of Physiology
- 1993-Present Seminars in Nephrology
- 1998- July Guest Editor, Seminars in Nephrology HIV and the Kidney
- 1994-2001 Journal of Molecular Medicine
- 1995-1999 Associate Editor, Journal of Molecular Medicine
- 1996-2001 Journal of the American Society of Nephrology
- 1997-2002 Associate Editor, American Journal of Kidney Disease
- 2001-Present American Journal of Physiology, Renal

#### Academic Advisory Committees

- 1984 Pew Research Awards Committee
- 1986 First Annual Alexis Carrel Conference Lipid mediators in Organ  
Transplantation: International Advisory Committee
- 1993 Sixth International Symposium on Basement Membrane:  
International Advisory Committee
- 1994 Seventh International Symposium on Basement Membranes:  
International Advisory Committee

#### Industry Advisory Committees

- 1998-Present Gilead Scientific Advisory Board
- 1998-Present Genzyme Ad Hoc Consultant
- 1999-Present Ariad Ad Hoc Consultant
- 2000-Present Coordinated Care Solutions Advisory Board
- 2000-Present Fibrogen Ad Hoc Consultant
- 2001-Present ANDRX Ad Hoc Consultant

#### American Heart Association

- 1990-1993 American Heart Association: Renal Study Section

#### Veteran's Administration

- 1985 Veteran's Administration: Career Development Study Section
- 1988, 1990-93 Nephrology Merit Review Board Study Section
- 1992-1993 Chairman, Nephrology Merit Review Board Study Section

#### American Federation for Medical Research

- 1984 AFMR Program Selection Committee

1986	AFCR Program Selection Committee
1987	AFCR Program Selection Committee
1982-85	AFCR Councilor: Southern Section Representative
<b>National Institutes of Health</b>	
1984	NIH/NHLBI: Study Section: Systolic Hypertension in the Elderly
1988-1990	NIH/NIDDK: Kidney Disease of Diabetes Mellitus
1989-1994	NIH: HIV Task Force Committee
1989-1994	NIH: Urologic and Renal Disease Committee
1989-1994	NIH/NIDR: Clinical Studies Committee
1989-1993	NIH/NIDR: Member Visiting Scholars Committee
1990-1994	NIH/NIDR: Chairman Visiting Scholars Committee
1993-1994	NIH/NIDR: Human Use Committee
1993-1994	NIH/NIAID: Advisory Member to the Office of AIDS Research
1993-1994	NIH/NCRR: Central Facilities Advisory Committee for the Veterinary Resources Program
1994-1996	NIH/OAR: Member Office of AIDS Research Planning Committee
1993-1994	NIH/NIAID: Study Section: National Cooperative Drug Discovery Groups for the Treatment of Human Immunodeficiency Virus Infection
1998	NIAID: Study Section: HIV Pathogenesis ad hoc
1999	NCI: Study Section: Oligonucleotide chemistry and therapy ad hoc
1999	NIDDK: Study Section: Center Grants for Polycystic Kidney Disease
<b>American and International Societies of Nephrology</b>	
1984	IXth Int. Congress of Nephrology, Program Committee
1984-86	Am. Soc. of Nephrology, Program Committee,
1990	Am. Soc. of Nephrology, Section Chairman & Program Committee
1993	Am. Soc. of Nephrology, Symposium Chairman: Gene Therapy
1994	Am. Soc. of Nephrology, Program Committee
1997-2002	Chairman, Homer Smith Award Committee American Society of Nephrology
1999	American Society of Nephrology Program Committee
2000	International Society of Nephrology: Frontiers in Nephrology "Gene Therapy" (Meeting Organizer)
2001	Program Committee, ASN/ISN
2002	Program Committee Chairman, ASN
<b>National Kidney Foundation</b>	
1990	Michigan Kidney Foundation Grant Awards Committee
1991-1995	National Kidney Foundation, Fellowship Rev. Committee
1995-Present	NY/NJ National Kidney Foundation Award Review Committee
1999-2001	Chairman, NKF Fellowship Review Committee (National)
1999-2001	Chairman, NKF Scientific Advisory Committee (National)
<b>Mt. Sinai Committees</b>	
1995-Present	Research Residency Program Committee, Mt. Sinai Medical Center
1995-Present	Housestaff Advisory Committee, Mt. Sinai Department of Medicine
1995-Present	Committee for Institutional Research Expansion
1996-Present	Director Research Residency Program, Mt. Sinai School of Medicine
1999-Present	Chairman, Ethical Conduct Committee, Mt. Sinai School of Medicine
1999-Present	Appointments and Promotions Committee, Dept. of Medicine Mt. Sinai
1998-Present	Housestaff Advisory Committee, Dept. of Medicine, Mt. Sinai
1998-Present	Housestaff Selection Committee, Dept. of Medicine, Mt. Sinai
1999-Present	Research Strategic Planning Committee, Mt. Sinai School of Medicine
1999-Present	Patient Oriented Research Committee, Mt. Sinai School of Medicine
2000-Present	Faculty Practice Executive Committee
2000-2001	Hunter Steering Committee

2000-2001  
2003-Present  
2003-Present

CEO and Dean Search Committees  
Vice President, Faculty Practice  
Chairman, Institutional Strategic Planning Committee

## PUBLICATIONS

### Original Peer-Reviewed Reports

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